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Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/FR00/00757	International filing date (day/month/year) 23 March 2000 (23.03.00)	Priority date (day/month/year) 26 March 1999 (26.03.99)
International Patent Classification (IPC) or national classification and IPC C07K 2/00		
Applicant MALINA, Halina		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 26 October 2000 (26.10.00)	Date of completion of this report 28 June 2001 (28.06.2001)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/FR00/00757

## I. Basis of the report

1. With regard to the **elements** of the international application:\*

- ☐ the international application as originally filed
- ☒ the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages 3,4//2,5,6//1, filed with the letter of 09.04.01/(15.06.01)/(21.06.01)
- ☒ the claims:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages 1-6, filed with the letter of 21 June 2001 (21.06.2001)
- ☐ the drawings:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/FR 00/00757

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims	1-6	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

## 2. Citations and explanations

Reference is made to the following documents:

**D1:** Kotake Y et al., JOURNAL OF BIOCHEMISTRY, Vol. 77, no. 3, March 1975 (1975-03), pages 685-687, **cited** in the application on page 1, line 7;

**D2:** Kobayashi K et al., CHEMICAL AND PHARMACEUTICAL BULLETIN, Vol. 28, no. 10, October 1980 (1980-10), pages 2960-2966, **cited** in the application on page 1, line 8.

1. Document **D1** discloses (the references in parentheses apply to this document) a compound (xanthurenic acid-insulin **complex** (title)) that is the product of the reaction of xanthurenic acid with insulin (insulin is a human protein) in a buffer solution or a serum (page 685, column 1, line 20 - column 2, line 2). Document **D1** also shows that said compound has immunological properties (abstract).

2. Document **D2** describes (the references in parentheses apply to this document) a compound resulting from the reaction of xanthurenic acid with BSA (page 2962, lines 37-38). Document **D2** shows that the bovine serum albumin (BSA, which is a mammal protein) is bonded to the xanthurenic acid (page

- 2962, line 39) via an electrostatic (page 2965, line 6) or water-repellent (page 2965, line 7) interaction.
3. The subject matter of Claim 1 therefore **differs** from said known compounds in that the bond between the xanthurenic acid and the protein is covalent.
  4. The subject matter of Claim 1 is therefore **novel** (PCT Article 33(2)).
  5. The **problem** addressed by the present invention can therefore be considered that of discovering alternative compounds that have immunological properties.
  6. The **solution** proposed in Claim 1 of the present application is considered to involve an **inventive** step (PCT Article 33(3)), for the following reason: The xanthurenic acid covalently bonded to a protein is a compound that cannot be derived from the available prior art documents (which only describe a complex (see § 1 above) or an electrostatic or water-repellent interaction (see § 2 above)).
  7. Claims 2-6 are dependent on Claim 1 and therefore also meet, as such, the PCT requirements of novelty and inventive step.
  8. Industrial applicability (PCT Article 33(4)):  
The subject matter of Claims 1 to 6 induces an immune response against diseases stemming from modifications in cellular physiology caused by xanthurenic acid (page 1, lines 3-5 and page 6, lines 10-16).